Amendment and Response Under 37 C.F.R. 1.116

Applicant: Jeffrey W. Chambers Serial No.: 10/812,250 Filed: March 29, 2004

Docket No.: C364.105.101 Title: STENT POSITIONING SYSTEM AND METHOD

## REMARKS

The following remarks are made in response to the Final Office Action mailed July 26, 2007. In that Office Action, claims 28-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lenker et al., U.S. Patent No. 5,683,451 ("Lenker") in view of Lam, U.S. Patent No. 5,607,444 ("Lam").

With this Response, claims 1-12 and 14-27 have been cancelled. Claims 28-41 remain pending in the application and are presented for consideration and allowance.

## 35 U.S.C. §103 Rejections

Claim 28 relates to a method of deploying an intravascular stent using a deployment site locator including a plurality of rods. The rods are extended and a <u>position of the ostium is determined</u> by contacting structures proximate the ostium with at least one of the rods. A stent is then delivered to a desired stent location, with the desired stent location being <u>based upon the determined position of the ostium</u>. Further, the stent is deployed at the desired stent location. None of the cited references teach or reasonably make obvious at least these features.

For example, the Office Action interprets the runners 42 of Lenker as being the "rods" of claim 28. While the runners/rods 42 may extend radially outwardly in an expanded state, Lenker does not teach or reasonably make obvious that the runners/rods 42 are used for stent positioning as otherwise asserted in the Office Action, let alone for determining a position of an ostium from which a desired stent location is found as set forth in claim 28. To the contrary, the method disclosed in Lenker is entirely different from that of claim 28. With the method of Lenker, the runners/rods 42 distribute the expansion load of the prosthesis 10 over the inner surface of a cover 32 prior to deployment. During deployment of the stent 10, the methodology of Lenker never entails distally extending the runners/rods 42 relative to the stent 10. As shown in FIGS. 5 and 6, during deployment of the stent 10, the runners/rods 42 are longitudinally aligned with a distall end of the prosthesis/stent 10. More particularly, prior to deployment, the stent 10 and the runners/rods 42 are entirely constrained within the cover 32 as shown in FIG. 5. The stent 10 is then simultaneously deployed with the runners/rods 42 by retracting the cover 32 as shown in FIG. 6. Finally, the runners/rods 42 are proximally retracted, allowing the stent 10 to expand

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against the bodily lumen as shown in FIG. 7. Lenker at col. 7, 1. 59 – col. 8, 1. 5. At no point with the stent deployment method of Lenker are the runners/rods 42 extended distal the stent 10; thus, it is impossible for Lenker to teach or reasonably make obvious at least the steps of "determining a position of the ostium by contacting structures proximate the ostium with at least one of the plurality of rods" or "delivering a stent through the guided catheter to a desired stent location, wherein the stent location is based upon the determined position of the ostium" as set forth in claim 28. To the contrary, the only teaching in Lenker of a method in which an ostium is possibly located is limited to fluoroscopy or radiography. Lenker at col. 10, 11. 44-63. Thus, several features of claim 28 are not met by Lenker.

Lam is similarly deficient. In particular, the stent deployment method disclosed in Lam provides a stent 20 having a collapsible tubular body 24 and permanently affixed pedals 27 extending distally from the tubular body 24. The stent 20 is deployed by first loading the tubular body 24/pedals 27 in a collapsed state onto a balloon 37 of a balloon catheter 23. The so-loaded balloon catheter 23 is then advanced into the patient's circulatory system. Lam at col. 6, 1l. 30-59. Based solely upon radiography, the stent 20 is positioned within the diseased portion 31 of a bifurcated vessel 21. Lam at col. 6, l. 66 - col. 7, l. 2. Subsequently, the balloon 37 is expanded to set the tubular body 24 within the diseased vessel 21, and the pedals 27 are expanded to "cap" the diseased portion 31. With the embodiment of FIG. 9 (relied upon by the Office Action), the stent 45 (unnumbered in the figure, but referenced in the text at column 9, lines 1-16) is comprised of a spring-like material, and a retaining sleeve 47 surrounds the entire stent 45 prior to deployment; as the retaining sleeve 47 is retracted, the pedals 27 expand as shown and as described above, engaging the diseased portion 31. Importantly, however, as with the Lenker methodology, this engagement by the pedals 27 is not used with the Lam method to "determine a position of the ostium" as otherwise required by claim 28. Rather, with the Lam approach, a desired position of the stent 20/45 is determined based only upon a visual estimate by the surgeon. That is to say, Lam does not teach or reasonably make obvious "determining a position of the ostium by contacting structures proximate the ostium with at least one of the plurality of rods." Instead, the pedals 27 are simply expanded/deployed at a best-guess location, and contact with the vessel 21/diseased portion 31 serves no purpose in determining desired positioning.

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In light of the above, neither Lenker nor Lam teaches each and every step of the method of claim 28. Modifying Lenker to deliver the stent 10 to an ostium in view of Lam does <u>not</u> result in a method by which the runners/rods 42 are deployed to determine a position of the ostium and then delivering a stent to a desired location based upon the determined position. Instead, with the techniques of both Lenker and Lam, the "rods" are deployed only <u>after</u> the ostium or other desired location has been grossly identified using fluoroscopy or other imaging techniques. For at least these reasons, then, claim 28 is allowable over the cited references. Claims 29-41 depend from claim 28 and thus are also allowable.

## CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 28-41 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 28-41 are respectfully requested. No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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